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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,219	12/28/2001	Christophe Ronsin	065691-0263	1844

22428 7590 04/08/2004

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,219	RONSIN ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *6,9-16,18-20,24-36,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,17,21-23 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: Ronsin *et al.*

Date of priority: 06/28/1999

Response to Amendment

The Amendment filed January 16, 2004 in response to the Office Action of August 25, 2003 is acknowledged and has been entered.

Claims 1-39 are pending.

Claims 6, 9-16, 18-20, 24-36, and 38-39 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1-5, 7-8, 17, 21-23, 37 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

Newly submitted claims 38-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 38-39 are directed to methods of inducing a T-specific immune response comprising administering peptides to a subject in need thereof. As set forth previously in the Action mailed August 25, 2003, only one product and one process of use of said product relate to a single general inventive concept.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 38-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

New Rejections:

Claim Rejections - 35 USC § 112

Claims 1-5, 7-8, 17, 21-23, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the claims are broadly inclusive of peptide compounds encoded by nucleotides 763 to 855 of Figure 4 (Claims 1, 4, 8, or 37) or a peptide encoded by nucleotides 763-855 (Claim 7), or peptides encoded by other nucleotides (i.e. 763-902, 763-1033, etc.) of Figure 4 (Claims 8, 37). However, recitation of nucleotide segments encoding particular polypeptides of Figure 4 is vague and indefinite because it is not clear from the specification and or the Figures what sequence identifier is associated with Figure 4. In other words, which polynucleotide sequence is present in Figure 4? This rejection can be obviated by canceling recitation of "Figure 4" in the claims, and inserting the appropriate sequence identifier.

Additionally, Claim 7, step B is vague for reciting "introducing a point modification or mutation at residue 4, 5, 6, 7, or 8" as it is not clear what residues comprise these particular positions. What sequence is associated with the residues?

Claims 4-5, and 7 are further vague and indefinite because it is not distinctly clear how the process or method clearly defines the preamble recitation of a claimed recombinant or

chemically synthesized peptide compound. This rejection can be obviated by amending the last step in Claims 4 and 5 to clearly indicate that what is identified is the peptide *compound*, not a peptide fragment.

Rejections Maintained:

Claims 2-5, and 7 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record in the Action mailed August 25, 2003.

Applicants argue (page 14) that the written description requirement ensures that the skilled artisan would understand, based on the specification, that the inventor possessed the claimed invention at the time the application was filed. Applicants further add that literal correspondence between the claims and the specification is not required. This argument has been considered but is not found persuasive. As set forth previously, the claims do not require that the polypeptide fragment(s) or the methods thereof possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to obtaining a genus of peptide compounds. However, the written description in this case only sets forth a recombinant peptide comprising SEQ ID NO:1 and a recombinant peptide consisting of SEQ ID NO:2 and therefore the written description is not commensurate in scope with the claims which read on an infinite number of variant peptides including those with certain percent identity, those with

modifications or mutations, elements other than natural amino acids, or wherein the peptide comprises a sequence of approximately 9 to 10 amino acids of SEQ ID NO:1. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 17, and 21-23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record in the Action mailed August 25, 2003.

The claims are drawn to pharmaceutical compositions wherein it is maintained that the teachings of the specification does not provide sufficient guidance and or objective evidence that such pharmaceutical compositions would predictably and effectively function as contemplated. Applicants argue (page 14) that the courts have recognized that absolute predictability is not a requirement for section 112 and that the amended claims are enabled. This argument has been considered but is not found persuasive. Applicant's arguments insufficiently address the unpredictability associated with pharmaceutical compositions that invoke peptide immunotherapy as set forth in the previous Action. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

April 6, 2004

Gary B Nickol

GARY NICKOL
PRIMARY EXAMINER